450. Misbranding of National Peerless Remedy. U. S. v. 23 Bottles of National Peerless Remedy. Default decree of condemnation and destruction. (F. D. C. No. 3512. Sample No. 50103-E.)

The label of this product not only failed to bear adequate directions and warning statements but also the common or usual name of each of the active ingredients, which included extracts of plant drugs including aloe.

On December 13, 1940, the United States attorney for the Middle District of Pennsylvania filed a libel against 23 bottles of National Peerless Remedy at Chambersburg, Pa., alleging that the article had been shipped by the National Pharmaceutical Manufacturing Co. from Baltimore, Md., on or about June 20, 1940; and charging that it was misbranded.

It was alleged to be misbranded (1) in that the label failed to bear adequate directions for use; (2) in that the label failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users; and (3) in that the label failed to bear the common or usual name of each active ingredient.

On June 16, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

451. Misbranding of O'D Easylax. U. S. v. 2 Gross Packages of O'D Easylax. Default decree of condemnation and destruction. (F. D. C. No. 3650. Sample No. 50056-E.)

In addition to failure to bear adequate warnings, the label of this product bore false and misleading therapeutic claims. It also failed to bear the required ingredient statement with the quantity or proportion of strychnine present; a statement of the quantity of contents; and the complete address of the manufacturer, packer, or distributor. Furthermore, the carton container was much taller than was necessary to hold its contents.

On January 9, 1941, the United States attorney for the District of Columbia filed a libel against 2 gross packages of O'D Easylax at Washington, D. C., alleging that the article was being offered for sale in the District of Columbia at Washington Wholesale Drug Exchange, Washington, D. C.; and charging that it was misbranded. It was labeled in part: "O'D Easylax * * * Liberty Drug Co. Washington, D. C."

Analysis of a sample of the article showed that it consisted essentially of phenolphthalein, aloin, strychnine, talc, and calcium carbonate together with a green coloring material.

It was alleged to be misbranded (1) in that labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application: (2) in that the following statements appearing on the label were false and misleading since it was not efficacious for the purposes recommended: (Carton) "They work naturally and form no habit * * * A Home Remedy for Indigestion Torpid Liver Chronic Constipation," and (bottle label) "They work naturally and form no habit. For Indigestion"; (3) in that the label did not bear the common or usual names of the active ingredients and a statement of the quantity or proportion of strychnine that it contained; (4) in that the carton and bottle label failed to bear the address of the manufacturer, packer, or distributor; (5) in that the bottle label failed to bear a statement of the quantity of contents; and (6) in that the container was so made, formed, or filled as to be misleading.

On February 4, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

452. Misbranding of Prunlax. U. S. v. 236 Bottles of Prunlax. Default decree of condemnation and destruction. (F. D. C. No. 3960. Sample No. 57020-E.)

On March 12, 1941, the United States attorney for the Eastern District of Missouri filed a libel against 31 12-fluid-ounce, 131 5-fluid-ounce, and 74 sample-sized packages of Prunlax at St. Louis, Mo., alleging that the article had been shipped by Adams Laboratories, Inc., from St. Louis, Mo., to Cleveland, Miss., on or about October 11, 1940, and that it had been shipped from Cleveland to St. Louis on or about October 14, 1940; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of extracts of plant materials including laxative plant drugs, sugar, glycerin, flavoring materials, and water, preserved with salicylic acid.

The article was alleged to be misbranded: (1) In that the directions (sample package) "Children One-quarter to one teaspoonful. Adults—One to two teaspoonfuls," and (remainder of product, bottle label) "Adjust dose to individual needs. And, taper off as action becomes normal. Children: According to age, one-quarter to one teaspoonful as needed. Adults: One to two teaspoonfuls night and morning until regulated," and (carton) "Dose: Children, 3 to 5 years, one-quarter teaspoonful; 5 to 9 years, one-half teaspoonful; 9 to 15, one teaspoonful. Adults, one to two teaspoonfuls night and morning until bowels act well," were not appropriate and were otherwise not adequate. (2) In that its labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users, since the labeling did not inform the purchaser that its use was contraindicated in cases of appendicitis and that frequent or continued use might result in dependence upon laxatives to move the bowels. (3) In that the name "Prunlax" was false and misleading since the active laxative ingredients in the preparation were not derived from prunes; in that the statement on the bottle labels, "To further promote its helpful harmony with health processes of the body, no phenolphthalein, alcohol, or other disturbing drug is used in Prunlax," was false and misleading since Prunlax cannot be depended upon to act in helpful harmony with health processes of the body, and the statement would tend to create the impression that the article contained no potentially harmful or deleterious ingredients, when such was not the case; and in that representations in the labeling that it was a safe laxative which would correct constipation without habit formation and without the use of irritating drugs; that it was especially helpful in cases of biliousness, sour stomach, colic due to gas, and diarrhea due to improper diet; and that it would prevent the user from having dizzy spells, were false and misleading since it would not be safe under all conditions and would not be efficacious for the disease conditions mentioned. (4) In that the sample-sized package failed to bear a label containing the common or usual name of each of its active ingredients. (5) In that the sample-sized package failed to bear a label containing a statement of the quantity of contents.

On May 3, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

453. Misbranding of Rogers Headache Soda. U. S. v. 95 Dozen and 3½ Dozen Packages of Rogers Headache Soda. Default decree of condemnation and destruction. (F. D. C. No. 4000. Sample Nos. 39686-E, 39700-E.)

This product contained acetanilid and its label did not bear adequate directions for use and such adequate warnings as are necessary for the protection of users. It contained not more than 1.9 grains of acetanilid per powder, whereas it was labeled as containing 2½ grains of acetanilid per powder. Its principal ingredient was not soda as suggested by its name.

On March 20, 1941, the United States attorney for the Eastern District of Illinois filed a libel against 95 dozen 10-cent packages and 3½ dozen 25-cent packages of Rogers Headache Soda at Cairo, Ill., alleging that the article had been shipped in interstate commerce on or about November 7, 1940, and February 4, 1941, by the Rogers Drug Co. from Memphis, Tenn.; and charging that it was misbranded.

The article was alleged to be misbranded in that the statements on the label, "Headache Soda—Each Powder Contains 2½ grs. Acetanilid," were false and misleading since they were incorrect. It was alleged to be misbranded further in that the label did not bear a statement of the quantity or proportion of acetanilid contained in the article; and in that the label did not bear adequate directions for use and adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users.

On April 26, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.